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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,442	04/22/2004	Lutz G. Guertler	5495.0001-10	6321

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
01/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,442	GUERTLER ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-53* is/are pending in the application.

4a) Of the above claim(s) *50-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply...*.

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of the communication filed 10 October, 2007. Claims 45-53 are pending in the instant application. This application contains claims 50-53 drawn to an invention non-elected with traverse. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

37 C.F.R. § 1.821-1.825

The specification is objected to for failing to comply with 37 C.F.R. § 1.821-1.825. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Applicants are reminded that nucleotide and/or amino acid sequences appearing in the specification, including the claims, require a sequence identifier. Claims 46 and 49 reference the amino acid sequence AAGSTM but fail to provide the requisite sequence identifier. Appropriate correction is required. Any questions regarding compliance with the sequence rules requirements specifically should be directed to the departments listed at the bottom of the Notice to Comply.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly

claiming the subject matter which the applicant regards as his invention.

Claims 45-49 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference an antigen comprising a peptide between 10-33 aa, 15-33 aa, or 16-33 aa, wherein said peptide comprises an amino acid sequence encoded by SEQ ID NO.: 35, in particular the amino acid sequence AAGSTM. As previously set forth, the referenced sequence is actually a sequencing primer (see pages 23 and 24 of the specification and the sequence listing) and does not appear to encode the antigen of interest. Page of the specification states that the sequence of interest is a PCR sequencing primer. Page 24 of the specification further notes that this sequence was used in a sequencing reaction. There is no discussion of the coding potential of this primer anywhere in the specification. Applicants contend that this primer can encode the claimed sequence if you use the second potential open reading frame. This argument is not persuasive given the data provided in the specification demonstrating that this is a sequencing primer.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

The previous rejection of claims 45-49 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, is hereby withdrawn in response to applicants' arguments.

New Matter

Claims 45-49 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). The claims reference "an amino acid sequence encoded by SEQ ID NO.: 35". This amino acid sequence is later identified as "AAGSTM". Additional claim limitations specify that the peptide comprising this epitope is between "a 10 amino acids in length to 33 amino acids", "15 amino acids in length to 33 amino acids in length", and "16 amino acids in length to 33 amino acids in length". Perusal of the disclosure fails to provide support for all of the claimed limitations. The only discussion of SEQ ID NO.: 35 is in the context of its utilization in a sequencing reaction. This sequence is

referenced repeatedly throughout the specification as a PCR sequencing primer. There is no indication that applicants contemplated making and/or using a polypeptide encoded by this sequence. Moreover, there is nothing in the disclosure that describes a peptide with the recited characteristics (i.e., comprising AAGSTM with the recited lengths).

Written Description

Claims 45-49 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Rochester*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (C.A.F.C. 2004). As previously set forth, the claims reference "an amino acid sequence encoded by SEQ ID NO.: 35". This amino acid sequence is later identified as "AAGSTM". Additional claim limitations specify that the peptide comprising this epitope is between "a 10 amino acids in length to 33 amino acids", "15 amino acids in length to 33 amino acids in length", and "16 amino acids in length to 33 amino acids in length". The issue raised in this rejection is whether or not applicants contemplated making and/or using polypeptides comprising the amino acid sequence AAGSTM from the recited sequence identifier (e.g., SEQ ID NO.: 35), as well as, peptides having the various size limitations set forth in the claims (e.g., 10-33aa; 15-33aa; 16-33aa).

The crux of the statutory requirement governing written description is whether one skilled in the art, familiar with the

practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, *cert. denied*, 469 U.S. 1209 (1985). *Texas Instruments, Inc.* v. *International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin* v. *Mayer*, 823 F2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor has **possession** of the claimed invention. See, e.g., *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The

claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. *Fujikawa* v. *Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1996).

The skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. First, the disclosure fails to set forth the epitope (e.g., AAGSTM) of interest anywhere in the disclosure. There is no discussion of generating or making polypeptides that have the recited sequence with the recited lengths. There is no sequence listing identifying the epitope of interest. Second, the disclosure fails to provide any data suggesting that applicants contemplated making a polypeptide from SEQ ID NO.: 35. The only discussion of this sequence is in the context of its utilization as a PCR sequencing primer, not as nucleic acid encoding the claimed epitope. For instance, at page 23, paragraph 062, the specification clearly states that an oligonucleotide synthesizer was used to make Primer 1 (or SEQ ID NO.: 35) for use as a PCR and sequencing primer. Page 24, paragraph 063, of the

disclosure clearly describes the utilization of this primer in an automated sequencing reaction. No other uses for this nucleotide sequence are contemplated or described. Finally, applicants assert that adequate support for the claimed invention is present, as evidenced by the fact that this sequence "could" encode a peptide comprising AAGSTM. Applicants are advised that this nucleotide sequence could potentially encode one of three different polypeptides depending upon the reading frame. For instance, in the (+1) frame, the sequence would actually encode SSRKHYX. In the (+2) frame, the sequence encodes XAAGSTMX. Finally, in the (+3) frame, the sequence encodes XQQEALW. There is no indication in the disclosure that applicants contemplated making and/or using a polypeptide encoded by the (+2) open reading frame. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed peptides at the time of filing.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was

published under Article 21(2) of such treaty in the English language.

Claims 45-49 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Luciw *et al.* (1992).[1] This teaching provides recombinant HIV-1 antigens that comprise a peptide corresponding to AAGSTM. Accordingly, this teaching meets all of the claimed limitations.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

[1] Applicants are advised that subject matter of interest was disclosed in the '447 application thereby giving this application an effective filing date of at least 06 September, 1985.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

24 December, 2007

Notice to Comply	Application No. 10/829,442	Applicant(s) Guertler, L. G., *et al.*	
	Examiner Jeffrey S. Parkin	Art Unit 1648	Paper No. 12/24/2007

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. § 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. § 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 F.R. 18230 (May 1, 1990), and 1114 O.G. 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 F.R. 29620 (June 1, 1998) and 1211 O.G. 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. § 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. § 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. § 1.822 and/or § 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. § 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" does not appear to be the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. § 1.821(e).

☒ 7. Other: Applicants are reminded that sequences appearing in the specification (including the claims) must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Applicant must provide appropriate amendments to the claims inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification and drawings.

Applicant May Need To Provide:

☒ An substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. § 1.821(e) or § 1.821(f) or § 1.821(g) or § 1.825(b) or § 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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